



Study of Efficacy and Safety of Pembrolizumab Plus Platinum-based Doublet Chemotherapy With or Without Canakinumab in Previously Untreated Locally Advanced or Metastatic Non-squamous and Squamous NSCLC Subjects (CANOPY 1)

20/08/2025 08:57:02

Main Information

Primary registry identifying number

LBCTR2019070214

Protocol number

CACZ885U2301

MOH registration number

11626/2019

Study registered at the country of origin

Yes

Study registered at the country of origin: Specify

Type of registration

Prospective

Type of registration: Justify

N/A

Date of registration in national regulatory agency

Primary sponsor

Novartis Pharma Services Inc.

Primary sponsor: Country of origin

Novartis Pharmaceuticals

Date of registration in primary registry

29/01/2020

Date of registration in national regulatory agency

Public title

Study of Efficacy and Safety of Pembrolizumab Plus Platinum-based Doublet Chemotherapy With or Without Canakinumab in Previously Untreated Locally Advanced or Metastatic Non-squamous and Squamous NSCLC Subjects (CANOPY 1)

Acronym

CANOPY 1

Scientific title

A Randomized, Double-blind, Placebo-controlled, Phase III Study Evaluating the Efficacy and Safety of Pembrolizumab Plus Platinum-based Doublet Chemotherapy With or Without Canakinumab as First Line Therapy for Locally Advanced or Metastatic Non-squamous and Squamous Non-small Cell Lung Cancer Subjects (CANOPY-1)

Acronym

Brief summary of the study: English

This is a phase III study of pembrolizumab plus platinum-based doublet chemotherapy with or without canakinumab in previously untreated locally advanced or metastatic non-squamous and squamous NSCLC subjects.

The study will assess primarily the safety and tolerability (safety run -in part) of pembrolizumab plus platinum-based doublet chemotherapy with canakinumab and then the efficacy (double-blind, randomized, placebo controlled part) of pembrolizumab plus platinum-based doublet chemotherapy with or without canakinumab.

Brief summary of the study: Arabic



دراسة مرحلة ثالثة عشوائية التوزيع مزدوجة التعمية مركزة على المقارنة بدواء وهمي لتقييم فعالية وسلامة دواء بمبروليزوماب بالإضافة إلى العلاج الكيميائي المزدوج القائم على البلاتين مع أو بدون كاناكينوماب كعلاج أساسي لدى المرضى المصابين بسرطان الرئة ذي الخلايا غير الصغيرة غير الحارشي والحارشي المتقدم محلياً أو النقلي (كانوبي-1)

Health conditions/problem studied: Specify

Patients with Non-Small Cell Lung Cancer

Interventions: Specify

•Drug: canakinumab
canakinumab every 3 weeks (squamous and non-squamous)

Other Name: ACZ885

•Drug: canakinumab matching placebo
canakinumab placebo every 3 weeks (squamous and non-squamous)

•Drug: pembrolizumab
200 mg every 3 weeks (squamous and non-squamous)

•Drug: carboplatin
AUC 5 mg/mL*min every 3 weeks (non-squamous) or AUC 6 mg/mL*min (squamous)

•Drug: cisplatin
75 mg/m² every 3 weeks (non-squamous)

•Drug: paclitaxel
200 mg/m² every 3 weeks (squamous)

•Drug: nab-paclitaxel
100 mg/m² every 3 weeks (squamous)

•Drug: pemetrexed
500 mg/m² every 3 weeks (non-squamous)

Key inclusion and exclusion criteria: Inclusion criteria

Key inclusion criteria:

- Histologically confirmed locally advanced stage IIIB or stage IV NSCLC for treatment in the first-line setting
- Known PD-L1 status determined by a Novartis designated central laboratory. A newly obtained tissue biopsy or an archival biopsy (block or slides) is required for PD-L1 determination (PD-L1 IHC 22C3 pharmDx assay), prior to study randomization. Note: For the safety run-in part, known PD-L1 status is not required.
- Eastern Cooperative oncology group (ECOG) performance status of 0 or 1.
- At least 1 measurable lesion by RECIST 1.1

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

90

Key inclusion and exclusion criteria: Exclusion criteria

Key exclusion criteria:

- Previous immunotherapy (e.g. anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CTLA-4 antibody, or any other antibody or drug specifically targeting T-cell co-stimulation or immune checkpoint pathways).
- Prior treatment with canakinumab or drugs of a similar mechanism of action (IL-1 β inhibitor).
- Subjects with epidermal growth factor receptor (EGFR) sensitizing mutations (identified in exons 19, 20, or 21), and/or ALK rearrangement by locally approved laboratory testing.
- Previously untreated or symptomatic central nervous system (CNS) metastases or lepto-meningeal disease.
- Subject with suspected or proven immune-compromised state or infections.
- Subject has prior to starting study drug: received live vaccination ≤ 3 months, had major surgery ≤ 4 weeks prior to starting study drug, has thoracic radiotherapy: lung fields ≤ 4 weeks, other anatomic sites ≤ 2 weeks, palliative radiotherapy for bone lesions ≤ 2 weeks.

Other protocol-defined inclusion/exclusion criteria may apply.

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

| | |
|---|--|
| Trial scope | Trial scope: Specify scope |
| Therapy | N/A |
| Study design: Allocation | Study design: Masking |
| Randomized controlled trial | Blinded (masking used) |
| Study design: Control | Study phase |
| Placebo | 3 |
| Study design: Purpose | Study design: Specify purpose |
| Treatment | N/A |
| Study design: Assignment | Study design: Specify assignment |
| Parallel | N/A |
| IMP has market authorization | IMP has market authorization: Specify |
| Yes, Worldwide | Argentina, Australia, Canada, Belgium, Bahrain, Brazil, Chile, Austria, Denmark, France, Germany, India, Italy, Japan... |
| Name of IMP | Year of authorization Month of authorization |
| Canakinumab (ACZ885) | |
| Type of IMP | |
| Immunological | |
| Pharmaceutical class | |
| Monoclonal Antibody-IL1B Inhibitor | |
| Therapeutic indication | |
| Histologically confirmed locally advanced stage IIIB or stage IV NSCLC | |
| Therapeutic benefit | |
| Progression free survival (PFS) per investigator assessment using RECIST v1.1 Overall response rate (ORR) per investigator assessment using RECIST v1. | |
| Study model | Study model: Explain model |
| N/A | N/A |
| Study model: Specify model | |
| N/A | |
| Time perspective | Time perspective: Explain time perspective |
| N/A | N/A |
| Time perspective: Specify perspective | |
| N/A | |
| Target follow-up duration | Target follow-up duration: Unit |
| | |
| Number of groups/cohorts | |
| | |
| Biospecimen retention | Biospecimen description |
| | |



Samples with DNA**

Lab specimen and tissue will be shipped to Quintiles (Q2) Central Lab in the UK. ctDNA Biomarker testing on shipped blood samples

Target sample size

10

Actual enrollment target size

8

Date of first enrollment: Type

Actual

Date of first enrollment: Date

05/11/2019

Date of study closure: Type

Actual

Date of study closure: Date

22/12/2022

Recruitment status

Other

Recruitment status: Specify

Recruitment closed however last patient in screening did not receive treatment

Date of completion

23/11/2022

IPD sharing statement plan

No

IPD sharing statement description

Novartis is committed to sharing with qualified external researchers, access to patient-level data and supporting clinical documents from eligible studies. These requests are reviewed and approved by an independent expert panel on the basis of scientific merit. All data provided is anonymized to respect the privacy of patients who have participated in the trial in line with applicable laws and regulations.

This trial data is currently available according to the process described on www.clinicalstudydatarequest.com.

Additional data URL

<https://clinicaltrials.gov/ct2/show/NCT03631199?term=CACZ885U2301&rank=1>

Admin comments

Trial status

Approved

Secondary Identifying Numbers

| Full name of issuing authority | Secondary identifying number |
|--------------------------------|------------------------------|
| Clinical Trials. gov | NCT03631199 |

Sources of Monetary or Material Support

| Name |
|-------------------------------|
| Novartis Pharma Services Inc. |



Secondary Sponsors

Name

NA

Contact for Public/Scientific Queries

| Contact type | Contact full name | Address | Country | Telephone | Email | Affiliation |
|--------------|-------------------|------------|---------|------------------------|-------------------------------|---------------------------------|
| Public | Fadi Farhat | Saida | Lebanon | 03 753 155 | drfadi.trials@gmail.com | Hammoud Hospital |
| Scientific | Hind Khairallah | Sin El Fil | Lebanon | +961 1 512002 Ext. 271 | Hind.Khairallah@fattal.com.lb | Khalil Fattal et Fils s.a.l. |
| Public | Joseph Kattan | Beirut | Lebanon | 03 635 913 | jkattan62@hotmail.com | Hotel Dieu De France |
| Public | Fadi El Karak | Beirut | Lebanon | 71 061 621 | felkarak@yahoo.com | Bellevue Medical Center |
| Public | Dany Abi Gerges | Bsalim | Lebanon | 03 341 960 | abigerges@gmail.com | Middle East Institute of Health |

Centers/Hospitals Involved in the Study

| Center/Hospital name | Name of principles investigator | Principles investigator speciality | Ethical approval |
|--|---------------------------------|------------------------------------|------------------|
| Hammoud Hospital University Medical Center | Dr Fadi Farhat | Hematology Oncology | Approved |
| Hotel Dieu De France | Dr Joseph Kattan | Hematology Oncology | Approved |
| Bellevue Medical Center | Dr Fadi El karak | Hematology Oncology | Approved |
| Middle East Institute of Health | Dr Dany Abi Gerges | Hematology Oncology | Approved |

Ethics Review

| Ethics approval obtained | Approval date | Contact name | Contact email | Contact phone |
|--|---------------|-----------------|-----------------------------|----------------------------|
| Hammoud Hospital University Medical Center | 20/12/2018 | Ahmad Zaatari | zaatari@hammoudhospital.com | +961 (0) 7 723111 ext 1160 |
| Hotel Dieu de France | 05/12/2018 | Nancy Alam | nancy.alam@usj.edu.lb | 01 421000 ext 2335 |
| Bellevue Medical Center | 01/03/2019 | Ghassan Maalouf | gmaalouf@bmc.com.lb | 1 682666 ext 7600 |
| Middle East Institute of Health | 30/05/2019 | Ahmad Ibrahim | ahmad_O_Ibrahim@hotmail.com | 961 (0) 3 233 560 |



Countries of Recruitment

| Name |
|--------------------------|
| Lebanon |
| Canada |
| France |
| Iceland |
| Germany |
| Japan |
| United States of America |
| Switzerland |
| Spain |

Health Conditions or Problems Studied

| Condition | Code | Keyword |
|----------------------------|---|---------|
| Non-Small Cell Lung Cancer | Malignant neoplasm of bronchus and lung (C34) | NSCLC |

Interventions

| Intervention | Description | Keyword |
|---|---|---------------------|
| Blood test (Hematology, Chemistry, Coagulation, PK, ct DNA, Biomarkers...), CT Scan, MRI, Whole body bone scan, Skin photography, Vital signs, Physical exam, Urinalysis, X-Ray | Blood test (Hematology, Chemistry, Coagulation, PK, ct DNA, Biomarkers...), CT Scan, MRI, Whole body bone scan, Skin photography, Vital signs, Physical exam, Urinalysis, X-Ray | ICF, IMP, Lab tests |

Primary Outcomes

| Name | Time Points | Measure |
|---|------------------|------------------|
| *To compare PFS by local investigator assessment as per RECIST1.1 | 6 months | 6 months |
| Progression free survival | During the study | during the study |



Key Secondary Outcomes

| Name | Time Points | Measure |
|--|------------------------------|--------------------------|
| •Overall response rate (ORR) per investigator assessment using RECIST v1.1 | baseline, 6 weekd and 12 wee | baseline, 6 weeks.. |
| •Patient reported outcome (PRO) | baseline and every visit | baseline and every visit |

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files